

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

MARC S. HERMELIN,

Defendant.

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NO. 4:10-CR-

85

**PLEA AGREEMENT, GUIDELINES  
RECOMMENDATIONS AND STIPULATIONS**

Come now the parties pursuant to Section 6B1.4, Sentencing Guidelines and Policy Statements (October 1987), and the Administrative Order of this Court (January 2, 1991) and hereby stipulate and agree that the following are the parties' agreements, recommendations, and stipulations:

**1. THE PARTIES:**

The parties to the agreements, recommendations, and stipulations contained herein are the defendant Marc S. Hermelin, defendant's counsel James Martin, Patrick Linehan, and Christopher B. Mead, and the Office of the United States Attorney for the Eastern District of Missouri and the Office of Consumer Litigation of the United States Department of Justice ("OCL") (hereinafter "the government"). This document and the agreements, recommendations, and stipulations contained herein do not, and are not intended to, bind any governmental office or agency other than the United States Attorney for the Eastern District of Missouri and OCL. It is understood by the parties that the Court is neither a party to nor bound by these agreements, recommendations and stipulations.

## **2. PLEA AGREEMENTS:**

### **A. The Plea:**

Pursuant to Rule 11(c)(1)(A), Federal Rules of Criminal Procedure, in exchange for the defendant's voluntary plea of guilty to Counts One -- Two of the Information, the Office of the United States Attorney for the Eastern District of Missouri and OCL agree that no further federal prosecution will be brought in this District against defendant arising from or related to defendant's conduct or any drug quality issues while employed or affiliated with KV Pharmaceutical (and its corporate subsidiaries) that violate the criminal provisions of the Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301-397 during the time period from January 1, 2005 to December 5, 2008 of which the Office of the United States Attorney for the Eastern District of Missouri and OCL are aware at this time.

Pursuant to Rule 11(c) and (d), Federal Rules of Criminal Procedure, the defendant fully understands that there will be no right to withdraw the plea entered under this agreement, except where the Court rejects those portions of the plea agreement which deal with charges the government agrees to dismiss or not to bring.

### **B. The Sentence:**

Pursuant to Rule 11(c)(1)(B), Federal Rules of Criminal Procedure, in this document the parties have addressed the United States Sentencing Guidelines, the factors set forth in 18 U.S.C. § 3553(a), and other factors relevant to sentencing. The parties agree that the recommendations contained herein fairly and accurately set forth the Guidelines applicable to this case. The parties believe that the Court should use these recommendations in determining the defendant's sentence along with any other factors specified in this agreement.

The parties acknowledge that the Guidelines application recommendations set forth herein are the result of negotiations between the parties as to the Guidelines applications they address and each party has a right to rely upon and hold the other party to the recommendations at the time of sentencing. The parties further agree that neither party shall request a sentence above or below the applicable guideline range pursuant to any chapter of the Guidelines, Title 18, United States Code, Section 3553(a), or any other provision or rule of law, except that defendant may move for a downward departure or variance because of his medical conditions while the United States may oppose any such motion. If the defendant makes such a motion, then defendant will provide the Court and the Government with all factual materials that support such a motion at least 30 days prior to sentencing. The parties understand that the District Court is neither a party to nor bound by the Guidelines recommendations agreed to in this document.

**C. Waiver of Post-Conviction Rights:**

(1) **Appeal:** The defendant has been fully apprised by defense counsel of the defendant's rights concerning appeal and fully understands the right to appeal the sentence under Title 18, United States Code, Section 3742.

(a) **Non-Sentencing Issues:** In the event the Court accepts the plea, as part of this agreement, both the defendant and the government hereby waive all rights to appeal all non-jurisdictional issues including, but not limited to, any issues relating to pre-trial motions, hearings and discovery and any issues relating to the negotiation, taking, or acceptance of the guilty plea or the factual basis for the plea.

(b) **Sentencing Issues:** Both the defendant and the government hereby waive all rights to appeal all sentencing issues other than the district court's application of the factors

enumerated in 18 U.S.C. § 3553 when imposing the ultimate sentence, including any issues relating to the determination of the Total Offense Level and the Criminal History Category.

(2) ***Habeas Corpus***: The defendant acknowledges being guilty of the crimes to which a plea is being entered, and further states that neither defense counsel nor the government has made representations which are not included in this document as to the sentence to be imposed. The defendant further agrees to waive all rights to contest the conviction or sentence in any post-conviction proceeding, including one pursuant to Title 28, United States Code, Section 2255, except for claims of prosecutorial misconduct or ineffective assistance of counsel.

**D. Disclosures Required by the United States Probation Office:**

The defendant agrees to complete and sign forms as required by the United States Probation Office prior to sentencing, including a Net Worth Statement (Probation Form 48); or a Net Worth Short Form Statement (Probation Form 48 EZ); a Cash Flow Statement (Probation Form 48B); a Declaration of Defendant or Offender Net Worth and Cash Flow Statements (Probation Form 48D); a Customer Consent and Authorization for Access to Financial Records (Probation Form 48E); and an Authorization to Release Government (State or Federal) Information to Probation Officer (Probation Form 11-H). The defendant agrees to provide complete, truthful and accurate information on these forms and consents to the release of these forms and any supporting documentation by the United States Probation Office to the government. The defendant also agrees to complete and sign forms, including a Customer Consent Authorization for Access to Financial Records During Supervision (Probation Form 48I), as required by the United States Probation Office during the defendant's term of supervised release or probation. The defendant agrees to provide complete, truthful, and accurate

information on these forms and consents to the release of these forms and any supporting documentation by the United States Probation Office to the government.

**E. Civil or Administrative Actions not Barred; Effect on Other Governmental Agencies:** The defendant has discussed with defense counsel and understands that nothing contained in this document is meant to limit the rights and authority of the United States of America to take any tax, civil, or administrative action of any kind against the defendant including, but not limited to deportation, exclusion, and any listing and debarment proceedings to restrict rights and opportunities of the defendant to manufacture or distribute drugs in the future or to contract or furnish items to, directly or indirectly, with government agencies. Further, any recommendation in this document as to the amount of loss or restitution is not binding upon the parties in any civil or administrative action by the government against the defendant. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning any issue arising under the Internal Revenue laws, Title 26 of the United States Code. This Plea Agreement does not bind the Internal Revenue Service of the Department of the Treasury, the Tax Division of the U.S. Department of Justice, or any other government agency with respect to the resolution of any criminal or civil tax issue.

**F. Cooperation:**

At this time, the defendant has discussed with defense counsel and understands that the government does not plan to file a motion for downward departure under Section 5K1.1 of the Guidelines or Title 18, United States Code, Section 3553, or both, or a motion under Fed. R. Crim. Proc. 35 after sentencing.

### **3. GUIDELINES RECOMMENDATIONS (NOT BINDING ON THE COURT):**

A. **Manual to be Used:** The parties recommend that the November 2009 version of the Guidelines Manual applies.

#### **B. Offense Conduct:**

(1) **Base Offense Level:** The parties recommend that the base offense level for Counts One and Two is 6 as found in U.S.S.G. § 2N2.1(a). The parties further recommend that no other Chapter 2 adjustments apply.

C. **Chapter 3 Adjustments:** The parties recommend that the following adjustments, other than acceptance of responsibility, apply: none.

D. **Acceptance of Responsibility:** The parties recommend that two (2) levels should be deducted pursuant to Section 3E1.1(b) because the defendant has clearly demonstrated acceptance of responsibility and timely notified the Government of an intention to plead guilty, for an adjusted offense level of 4.

The parties agree that if the defendant does not abide by all of the agreements made within this document, the defendant's failure to comply is grounds for the loss of acceptance of responsibility pursuant to Section 3E1.1. The parties further agree that the defendant's eligibility for a reduction pursuant to Section 3E1.1 is based upon the information known at the present time and that any actions of the defendant which occur or which become known to the government subsequent to this agreement and are inconsistent with the defendant's acceptance of responsibility including, but not limited to criminal conduct, are grounds for the loss of acceptance of responsibility pursuant to Section 3E1.1. In any event, the parties agree that all of the remaining provisions of this agreement remain valid and in full force and effect.

E. **Other Adjustment(s):** Under U.S.S.G. § 3D1.2(b), counts one and two involve the same victim and were part of a common plan. Therefore, these Counts are grouped together into one group for sentencing guidelines purposes.

F. **Estimated Total Offense Level:** Based on these recommendations, the parties estimate that the Total Offense Level and Combined Offense Level is four (4).

G. **Criminal History:** The determination of the defendant's Criminal History Category shall be left to the Court after it reviews the Presentence Report, unless the Court agrees with the defendant that no presentence report is necessary. The Criminal History Category determination will be made only after the United States Probation Office obtains and evaluates the records it can find of the defendant's criminal history. Prior convictions can affect the sentence and usually result in a harsher sentence. Both parties retain their right to challenge and present arguments, before sentencing, any finding as to the defendant's criminal history and the applicable category. The parties are not aware of any criminal history of the defendant at the time when the plea agreement was signed.

Both parties are aware that the results of a preliminary criminal record check are available for review in the Pretrial Services Report.

**H. Acknowledgment of Effect of Recommendations:**

The parties recognize that they may not have addressed or foreseen all the Guidelines provisions applicable in this case. Guidelines applications not expressly addressed by the parties' recommendations, but which are addressed by the Presentence Report or the Court, may be presented to the Court for consideration. The parties agree and understand that the Court, in its discretion, may apply any Guidelines not addressed in this document.

Furthermore, this Court is not bound by these recommendations. The refusal of this Court to follow the recommendations of the parties shall not serve as a basis to withdraw the plea.

#### **4. STIPULATION OF FACTS RELEVANT TO SENTENCING:**

Venue for Counts One and Two of the Information is proper within the Eastern District of Missouri and Defendant expressly waives any claim or challenge to venue as alleged within these Counts.

Except for ¶ 19 of the Information, the parties stipulate and agree that all facts in the Information filed in this case are true. The parties each may offer evidence and argument regarding the issues discussed in ¶ 19 of the Information at or before sentencing. Further, the parties stipulate and agree that the facts in this case are as follows and that the government would prove all of the facts in the Information (except ¶ 19) and the facts discussed below beyond a reasonable doubt:

Hermelin was a responsible corporate officer of both drug manufacturer KV Pharmaceutical ("KV") and its subsidiary Ethex Corporation ("Ethex"), with the authority and responsibility to prevent and correct violations of the Food, Drug, and Cosmetic Act with respect to KV and Ethex.

On or about April 16, 2008, in St. Louis County, Missouri, within the Eastern District of Missouri, MARC S. HERMELIN, defendant herein, was a responsible corporate officer of KV under 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a)-(b) and during that time that KV introduced and caused the introduction and delivery into interstate commerce of a quantity of the drug morphine sulfate, 60 milligram strength, from St. Louis County, Missouri to San Francisco,



California, that was misbranded within the meaning of the Food, Drug, and Cosmetic Act because the drug's labeling was false and misleading in that it stated that the drug was a uniform strength when a tablet of the drug was actually oversized and contained more of the drug than the labeling's stated amount of 60 milligrams.

Moreover, on or about December 19, 2007, in St. Louis County, Missouri, within the Eastern District of Missouri, MARC S. HERMELIN, defendant herein, was a responsible corporate officer of KV under 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a)-(b) and during that time that KV introduced and caused the introduction and delivery into interstate commerce of a quantity of the drug morphine sulfate, 30 milligram strength, from St. Louis County, Missouri to Canada, that was misbranded within the meaning of the Food, Drug, and Cosmetic Act because the drug's labeling was false and misleading in that it stated that the drug was a uniform strength when a tablet of the drug was actually oversized and contained more of the drug than the labeling's stated amount of 30 milligrams.

For the purposes of this agreement, Defendant derived pecuniary gain from these offenses as an responsible corporate officer of KV and Ethex, and the gross gain from these offenses is approximately \$500,000. The Defendant and the government agree that the facts set forth above are true and may be considered as "relevant conduct" pursuant to Section 1B1.3.

#### **5. ELEMENTS OF THE OFFENSE:**

As to Counts One and Two of the charges, the defendant admits that:

First, defendant was a responsible corporate officer of KV, a drug company; and,

Second, the defendant held this corporate position when KV caused the introduction and delivery of a drug into interstate commerce, and;

Third, the drug was misbranded when introduced into interstate commerce in that the drug's labeling was false and misleading regarding the amount of the active ingredient that the drug actually contained.

[Proof of defendant's intent to defraud or mislead is not required as an element of these crimes, as the Food, Drug, and Cosmetic Act creates "strict liability" for misdemeanor offenses. United States v. Park, 421 U.S. 658, 672-74 (1975).]

## **6. PENALTIES:**

**A. Statutory Penalties:** The defendant fully understands that the maximum possible penalty provided by law for each count in the Information to which the defendant is pleading guilty is imprisonment of not more than one year, a fine of not more than \$100,000, or both such imprisonment and fine. Alternatively, if any person derives pecuniary gain from the offense, or if the offense results in a pecuniary loss to a person other than the defendant, then the Court may also impose a fine not more than the greater of twice the gross gain or gross loss. In addition, the Court may also impose a period of supervised release of not more than one year.

**B. Sentencing Guidelines Effect on Penalties:** The defendant understands that except for Title 18, Sections 3553(b)(1) and Section 3742 (e), this offense is affected by the provisions and Guidelines of the "Sentencing Reform Act of 1984," Title 18, United States Code, Sections 3661 *et. seq.* and Title 28, United States Code, Section 994.

**C. Supervised Release:** The defendant understands that the Court may impose a term of "supervised release" to follow incarceration pursuant to Title 18, United States Code, Section 3583 (Sentencing Guidelines, Chap. 5, Part D). The defendant further understands that pursuant to the supervised release term, the Court will impose standard conditions upon the defendant and may impose special conditions upon the defendant which relate to the crime the defendant committed. These conditions will be restrictions on the defendant to which the defendant will be

required to adhere. The defendant further understands that violation of the conditions of the term of supervised release resulting in revocation may require the defendant to serve a term of imprisonment equal to the length of the term of supervised release, but not greater than the term set forth in Title 18, United States Code, Section 3583(e)(3), without credit for the time served after release. The defendant understands that parole has been abolished.

**D. Mandatory Special Assessment:** The defendant further acknowledges that this offense is subject to the provisions of the Criminal Fines Improvement Act of 1987 and that the Court is required to impose a mandatory special assessment of \$25.00 per count for a total of \$50.00, which defendant agrees to pay at the time of sentencing. 18 U.S.C. § 3013(a)(1)(A)(iii). The defendant further agrees that if the mandatory special assessment imposed by the Court is not paid at the time of sentencing, until the full amount of the mandatory special assessment is paid, money paid by the defendant toward any restitution or fine imposed by the Court shall be first used to pay the mandatory special assessment.

**E. Possibility of Detention:** The defendant acknowledges that upon entering the plea of guilty as contemplated in this document, the defendant may be subject to immediate detention pursuant to the provisions of Title 18, United States Code, Section 3143.

## **7. FINES, RESTITUTION AND COSTS**

The defendant understands that the Court may impose a fine, restitution (in addition to any penalty authorized by law), costs of incarceration and costs of supervision.

**A. Restitution:** The defendant further acknowledges that pursuant to Title 18, United States Code, Section 3663A, an order of restitution is mandatory for all crimes listed in Section 3663A committed after April 24, 1996. Pursuant to 18 U.S.C. § 3663A(a)(1) and

§ 3663A(c)(3)(B), the parties recommend that no restitution award be made, in light of the restitution already provided to the Medicare and Medicaid programs in *United States v. Ethex Corporation*, ED MO Case No. 4:10 CR 117 (ERW). Defendant further reserves the right to argue that the no restitution is required under the law.

**B. Effect of Bankruptcy on Fines or Restitution:** The defendant hereby stipulates that any fine or restitution obligation imposed by the Court is not dischargeable in any case commenced by the defendant or the defendant's creditors pursuant to the Bankruptcy Code. The defendant agrees not to attempt to avoid paying any fine or restitution imposed by the Court through any proceeding pursuant to the United States Bankruptcy Code, and stipulates that enforcement of any fine or restitution obligation by the United States or a victim is not barred or affected by the automatic stay provisions of the United States Bankruptcy Code (Title 11, United States Code, Section 362).

**C. Forfeiture.** In addition to the recommended fine set forth in this plea agreement, defendant will not contest an administrative forfeiture of \$900,000 in United States currency pursuant to 18 U.S.C. § 981. Defendant acknowledges and agrees to forfeit all rights, title, and interest in these funds and not oppose whatever steps are necessary to pass clear title of these funds to the United States, including but not limited to waiving any rights to file a claim contesting the forfeiture. Defendant agrees that at sentencing he shall remit the amount of \$900,000 to the United States pursuant to instructions provided by the United States. Defendant and the United States Attorney's Office agree that this payment shall satisfy any and all forfeiture obligations defendant may have as a result of the guilty plea.

Forfeiture of substitute assets shall not be deemed to be an alteration of defendant's sentence. This forfeiture shall neither satisfy nor offset any fine, restitution, or other penalty imposed upon defendant nor be used to offset defendant's tax liability or any other debt owed to the United States.

In addition to all other waivers or releases set forth in this Agreement, defendant hereby waives any and all claims arising from or relating to the forfeiture discussed in this section, including, without limitation, any claims arising under the Double Jeopardy clause of the Fifth Amendment or the Excessive Fines clause of the Eighth Amendment of the United States Constitution, or any other provision of federal or state law. The District Court for the Eastern District of Missouri shall retain jurisdiction to enforce the provisions of this section.

**D. Fine.** Pursuant to 18 U.S.C. § 3571(d), the maximum statutory fine is \$1,000,000, twice the defendant's gross gain from the offense. The parties jointly recommend a fine of \$1,000,000. Defendant agrees to make full payment of the fine within ten days of sentencing. If defendant fails to make any payment due under this paragraph, at anytime 5 calendar days after the payment was due, the United States Attorney's Office, in its sole discretion, may void this plea agreement, keep any payments already made before the plea agreement was voided, and prosecute defendant, using, among other evidence, the admissions made in this agreement.

#### **8. ACKNOWLEDGMENT AND WAIVER OF THE DEFENDANT'S RIGHTS:**

The defendant acknowledges and fully understands the following rights: the right to plead not guilty to the charges; the right to be tried by a jury in a public and speedy trial; the right to file pre-trial motions, including motions to suppress evidence; the right at such trial to a

presumption of innocence; the right to require the government to prove the entire case against the defendant beyond a reasonable doubt; the right not to testify; the right not to present any evidence; the right to be protected from compelled self-incrimination; the right at trial to confront and cross-examine adverse witnesses; the right to testify and present evidence; and the right to compel the attendance of witnesses. The defendant further understands that by this guilty plea, the defendant expressly waives all the rights set forth in this paragraph.

The defendant fully understands that the defendant has the right to be represented by counsel, and if necessary, to have the Court appoint counsel at trial and at every other stage of the proceeding. The defendant's counsel has explained these rights and the consequences of the waiver of these rights. The defendant fully understands that, as a result of the guilty plea, no trial will, in fact, occur and that the only action remaining to be taken in this case is the imposition of the sentence.

The defendant is fully satisfied with the representation received from defense counsel. The defendant has reviewed the government's evidence and discussed the government's case and all possible defenses and defense witnesses with defense counsel. Defense counsel has completely and satisfactorily explored all areas which the defendant has requested relative to the government's case and any defenses.

#### **9. PRESENTENCE REPORT AND SENTENCING:**

Following defendant's guilty plea, defendant may move the Court to waive the preparation of a Presentence Report, on which the Government reserves the right to oppose this motion and provide the Court with any information relevant to sentencing. If the Court denies any such motion by defendant, then a Presentence Report will be prepared. At the time of

sentencing, the parties reserve the right to allocution regarding the appropriate sentence to be imposed. Each party also reserves the right to bring any misstatements of fact made either by the other party or on that party's behalf to the attention of the Court at the time of sentencing.

**10. STANDARD OF INTERPRETATION:**

In interpreting this document, any drafting errors or ambiguities shall not automatically be construed against any party, whether or not the party was involved in drafting this document.

**11. VOLUNTARY NATURE OF THE PLEA AND THE PLEA AGREEMENT, RECOMMENDATIONS AND STIPULATIONS:**

This document constitutes the entire agreement between the defendant and the government, and no other promises or inducements have been made, directly or indirectly, by any agent of the government, including any Department of Justice attorney, concerning any plea to be entered in this case or the agreements, recommendations or stipulations contained herein. In addition, the defendant states that no person has, directly or indirectly, threatened or coerced the defendant to do or refrain from doing anything in connection with any aspect of this case, including entering a plea of guilty. The defendant's agreements, recommendations and stipulations as set forth above are made in exchange for the agreements, recommendations and stipulations set forth in this document.

The defendant acknowledges that the defendant has voluntarily entered into both this plea and these agreements, recommendations and stipulations. The defendant further acknowledges that this guilty plea is made of the defendant's own free will because the defendant is, in fact, guilty of the conduct specified in sections four and five above.

**12. CONSEQUENCES OF FURTHER CRIMINAL CONDUCT OR WITHDRAWAL OF PLEA BY DEFENDANT:**

The defendant agrees that if, between the time of signing this document and the sentencing the defendant engages in any criminal activity, the government shall be released from any obligations or limits on its power to prosecute the defendant created by this document, and any such conduct shall be grounds for the loss of acceptance of responsibility pursuant to Section 3E1.1.

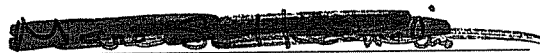
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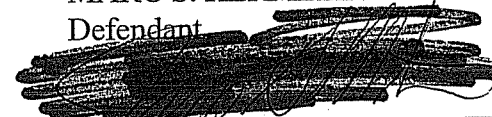
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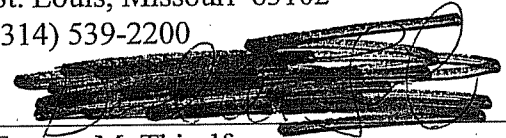
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MARC S. HERMELIN  
Defendant

  
James Martin  
Patrick Linehan  
Christopher B. Mead  
Attorneys for Defendant

  
Andrew J. Lay, #28542  
Assistant United States Attorney  
111 South 10th Street, Room 20.333  
St. Louis, Missouri 63102  
(314) 539-2200

  
Eugene M. Thierolf  
David A. Frank  
Office of Consumer Litigation  
U.S. Department of Justice  
P.O. Box 386  
Washington, D.C. 20044  
(202) 616-0219